

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

**FDA PUBLIC MEETING ON IMPLEMENTING THE *PEARSON* COURT
DECISION AND OTHER HEALTH CLAIM ISSUES**

PREPARED TESTIMONY OF

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The Center for Science in the Public Interest (CSPI) appreciates this opportunity to present our views on the level of scientific support necessary for health claims for dietary supplements.¹

The Food and Drug Administration (FDA) has required that health claims for dietary supplements be supported by “significant scientific agreement.”² In the absence of such agreement, the FDA considers health claims to be misleading. The U.S. Court of Appeals for the District of Columbia Circuit held in *Pearson v. Shalala*³ that based on the administrative record before it, the FDA must consider whether the use of a disclaimer would eliminate the potential for deception before it decides to prohibit health claims not supported by significant scientific agreement.

The Court, however, created several major exceptions to its overall holding and discussed situations in which disclaimers would not be sufficient to prevent consumer deception. These include situations in which:

- Permitting a health claim not supported by significant scientific agreement would threaten consumer health and safety;
- Scientific evidence supporting a health claim is outweighed by evidence that is qualitatively or quantitatively superior;
- Empirical evidence demonstrates that a disclaimer is insufficient to protect consumers from deception.

¹ CSPI is a non-profit consumer organization supported by almost 1,000,000 members that has worked since 1971 to improve national health policies.

² 21 C.F.R. § 101.14(c).

³ 164 F.3d 650 (D.C. Cir. 1999).

These exceptions to the Court's holding significantly limit the number and types of health claims that can be made in the absence of significant scientific agreement. Today, I am releasing a letter from 15 national public health, medical, and consumer organizations to Joseph A. Levitt, Director of the FDA Center for Food Safety and Applied Nutrition, that urges the agency to fully implement this portion of the Court's decision.⁴ I will now discuss each of these exceptions to the Court's overall holding.

I. The FDA is not obligated to consider using the disclaimer approach when a preliminary health claim raises health and safety concerns.

At the outset, it should be emphasized that the Court's overall holding was premised on the basis that the supplements at issue in the case do not "in any fashion threaten consumers' health and safety."⁵ However, there has been a steady stream of reports concerning the hazards of dietary supplements. The Washington Post, for example, ran this front page article last month that proclaimed "Herbal Products Boom Take Human Toll."⁶ The government apparently did a poor job of bringing this type of information to the Court's attention, and the Court simplistically assumed that supplements in general posed no hazard. In light of this naive assumption, the relevance of the Court's primary holding is quite limited. As the Court noted, "the government may have more leeway in choosing suppression over disclosure as a response to the problem of

⁴ The organizations signing this letter include the American Heart Association, the American Cancer Society, the American Dietetic Association, the American Association of Retired Persons, and the Consumer Federation of America.

⁵ *Pearson* at 656.

⁶ Guy Gugliotta, *Health Concerns Grow Over Herbal Aids; As Industry Booms, Analysis Suggests Rising Toll in Illness and Death*, Wash. Post, Mar. 19, 2000, at A1, A22.

consumer confusion where the product *affects health*.”⁷ Health claims for dietary supplements that are not supported by significant scientific agreement can have an adverse impact on health in several different ways.

A. The FDA need not consider using the disclaimer approach where claims relate to essential bodily organs or serious health conditions.

Under the Court’s opinion, the FDA need not and should not consider using the disclaimer approach if a proposed health claim not based on significant scientific agreement pertains to an essential organ or a serious health condition. This would include, for example, claims regarding the heart, lung, brain and liver. This exception to the Court’s holding also pertains to claims regarding serious health conditions including risk factors for cancer and heart disease, as well as asthma, birth defects, diabetes, HIV, and Alzheimer’s disease. The Court recognized that in situations where either consumer health or safety is involved, claims supported by preliminary scientific evidence would be inappropriate even if accompanied by a disclaimer.

The Court’s holding on this point is well-grounded. For example, in the 1990’s beta carotene supplements were being promoted by the supplement industry as substances that might reduce the risk of cancer. Preliminary epidemiological studies had demonstrated a promising link between the consumption of beta carotene rich foods and a reduced risk of cancer. Clinical studies conducted afterwards, however, showed strong evidence of *no* benefit from beta carotene supplements and indicated that the use of such products by smokers might actually increase their risk of lung cancer.⁸ Additional clinical studies funded by the National Institutes of Health

⁷ *Pearson* at 659 (emphasis added).

⁸ National Cancer Institute, Press Release, *Beta Carotene and Vitamin A Halted in Lung Cancer Prevention Trial*, Jan. 18, 1996.

confirmed these findings and led the researchers to discontinue the studies.⁹

Therefore, it is essential that claims that a substance can reduce the risk of a serious disease like cancer should only be permitted where significant scientific agreement exists; under the Court's holding, the FDA is not obligated to permit such claims on the basis of preliminary evidence.

B. The FDA need not consider using the disclaimer approach when it is foreseeable that consumers may, based on a preliminary claim, forego a proven dietary or medical therapy in favor of a dietary supplement that may or may not be beneficial to health.

As the Court recognized, the FDA may choose to suppress claims not supported by significant scientific agreement instead of permitting them with a disclaimer in situations where a supplement "affects health."¹⁰ Preliminary claims for dietary supplements that may or may not be beneficial can cause injury to health if consumers choose them over proven dietary or medical therapies. Thus under the Court's holding, the FDA is not obligated to permit preliminary health claims with a disclaimer if the claim would lead consumers to rely on an unproven dietary supplement instead of a proven dietary or medical therapy.

A survey conducted by *Prevention Magazine* with technical assistance from the FDA estimates that consumers often substitute unproven dietary supplements for proven therapeutic approaches even in the absence of preliminary health claims. According to this survey, 22.8 million consumers used dietary supplements *instead* of prescription medicine, and 30.3 million used herbal remedies *instead* of an over-the-counter drug. Thus, it is evident that supplements --

⁹ *Id.*

¹⁰ *Pearson* at 659.

which largely have not been tested for safety and efficacy -- have already replaced many prescription and over-the-counter drugs that have been demonstrated to be safe and effective. The use of preliminary health claims would surely exacerbate this trend and cause additional injury to consumer health. As the Prevention survey concluded:

Already, an estimated 11.9 consumers have experienced adverse reactions from using herbal remedies, and 6.5 million have had problems of this kind when using specialty supplements.¹¹

To permit health claims to be made on a basis other than significant scientific agreement presents an unnecessary and unjustified threat to consumer health, especially when the claim may encourage consumers to forego a proven dietary or medical treatment in favor of a supplement that may or may not work. In such situations, the use of a disclaimer approach is an insufficient means of protecting consumer health and safety, and, under the Court's opinion, the FDA may instead prohibit the claim completely.

C. The FDA need not consider using the disclaimer approach when consumers, based on their own observations, cannot determine whether a claim is true.

Consumers who rely on preliminary health claims and take dietary supplements promoted for conditions that are difficult to self-diagnose have no way of knowing whether the products are working. The use of preliminary health claims not supported by significant scientific agreement is particularly dangerous in such cases because they may lead consumers to rely on treatments that may not be effective. The Court's decision in *Pearson* does not require the FDA to approve

¹¹ *Prevention Magazine's National Survey on Self-care Reveals 158 Million Consumers Use Dietary Supplements for Their Health and Spend Approximately \$8.5 Billion Each Year; Survey Also Reports That Widespread Use of Dietary Supplements May Cause Public Health Problems*, PR Newswire, Feb. 25, 2000.

preliminary claims with a disclaimer if the health and safety of consumers are threatened as it is in this situation.

II. The FDA is not obligated to consider the disclaimer approach when scientific evidence supporting a claim is outweighed by quantitatively or qualitatively superior evidence.

In *Pearson*, the Court stated that the FDA can prohibit preliminary health claims where the scientific evidence in support of the claim is outweighed by the evidence against the claim, or where the evidence supporting it is qualitatively weaker than the evidence against it. The Court's decision thus calls on the FDA to weigh and evaluate the scientific evidence in support of a claim. If studies in support of a claim are qualitatively weaker than studies siding against a claim, then the claim may be prohibited. Also, if the number of studies demonstrating that a claim is invalid is larger than the number of studies supporting the claim, the FDA may prohibit the claim completely. We believe this exception to the Court's primary holding is very broad, and will apply to many of the decisions that the FDA will face in this area.

III. The FDA is not obligated to consider permitting preliminary health claims with a disclaimer when empirical evidence shows that the disclaimer is insufficient to protect consumers from deception.

The Court in *Pearson* stated that disclaimers would not be required where "empirical evidence that disclaimers similar to the ones . . . suggested. . . [by the court] would bewilder consumers and fail to correct for deceptiveness. . . ." ¹²

The FDA should thus conduct research so that it can obtain empirical evidence demonstrating when disclaimers do not prevent consumer deception caused by health claims that

¹² *Pearson* at 659-660.

fail to meet the significant scientific agreement standard. A study conducted by the Federal Trade Commission on health claims in advertising concludes that certain disclaimers are insufficient to protect consumers.¹³ The FDA should conduct its own research on dietary supplement label claims.

We note that under the Supreme Court doctrine in this area, a disclaimer approach is traditionally used to provide consumers with additional information to remedy a deceptive claim and help them choose between products or services. In the leading case, *Zauderer v. Office of Disciplinary Counsel*, an attorney had advertised that he accepted cases on a contingency basis with “no cost” to the client. The Supreme Court upheld an Ohio Bar rule requiring the lawyer to disclose that clients were still responsible for paying costs if the litigation were unsuccessful.

Similarly, in the dietary supplement area, a disclaimer providing additional information would be appropriate where there was significant scientific agreement that a substance produced a desired effect, but that other factors played an important role as well. For example, if the truthfulness of a health claim for an herbal substance is dependent upon consuming it with a diet low in fat, then that disclosure would be material to consumers.

The examples of the disclaimers suggested by the *Pearson* court, however,¹⁴ do not provide consumers with any useful additional information to help them evaluate the safety and

¹³ e.g., Federal Trade Commission, Generic Copy Test of Food Health Claims in Advertising, Nov. 1998. For example, the FTC found that where disclaimers were used to inform consumers that a product high in one beneficial nutrient also contained high levels of another nutrient that could increase the risk of a diet-related disease, almost half of those surveyed “apparently misconstrued the dietary warning as a favorable commentary on the quantity of sodium or saturated fat in the advertised products.” *Id.* at E. 3-4.

¹⁴ “The FDA does not approve this claim” or “the evidence in support of this claim is inconclusive.” *Pearson* at 659.

health benefits of a supplement. Simply informing consumers that the scientific evidence is inconclusive and/or that the FDA has not approved a claim merely constitutes a disclaimer of responsibility; such statements do not provide consumers with additional useful information that remedies an otherwise misleading claim.¹⁵ There is a vast difference between merely disclaiming responsibility and disclosing useful information that qualifies an otherwise deceptive statement. While the Court expressed confidence in the specific wording of the disclaimers that it suggested the FDA utilize, it did not “rule out the possibility”¹⁶ that its suggested approach would “bewilder consumers and fail to correct for deceptiveness.”¹⁷ It is, therefore, incumbent upon the FDA to conduct the necessary consumer research and resolve the Court’s uncertainty about its holding.

IV. Conclusion

The *Pearson* decision, by its own terms, significantly limits the applicability of its primary holding to the FDA’s health claim review process. In the absence of significant scientific agreement, the FDA is not required to approve a health claim if:

- Permitting a health claim not supported by significant scientific agreement would threaten consumer health and safety;
- Scientific evidence supporting a health claim is outweighed by evidence that is qualitatively or quantitatively superior;
- Empirical evidence demonstrates that a disclaimer is insufficient to protect consumers from deception.

¹⁵ David C. Vladeck, *Devaluing Truth: Unverified Health Claims in the Aftermath of Pearson v. Shalala*, 54 Food and Drug L.J., 535-554 (1999).

¹⁶ *Pearson* at 660.

¹⁷ *Id.* at 659-60.

Each of these factors must be addressed by the FDA before any health claim not supported by significant scientific agreement is permitted.